

Valdosta State University
INSTITUTIONAL REVIEW BOARD (IRB)

Guidance on Obtaining and Documenting Informed Consent

The Informed Consent Process

Obtaining an individual's consent to participate, or a parent's permission to include his/her child, in a research study is a requirement of the ethical principles of human research and the Federal regulations to which Valdosta State University adhere. An Informed Consent (or Parental Permission Form) serves as the documentation of the informed consent process in which the researcher should:

- ◆ Clearly explain to the participant (or parent) in terms that he/she can understand given his/her educational or cognitive functioning level:
 - The purpose of the research;
 - The nature and duration of the research procedures;
 - The potential risks and benefits of participation;
 - Costs and compensation of participation (if any);
 - The voluntary nature of participation; and
 - How information about participants will be safeguarded to ensure confidentiality;
- ◆ Provide the opportunity for potential participants (or parents) to ask questions; and
- ◆ Ensure adequate time for potential participants (or parents) to reflect and decide whether they wish to participate in the research (or allow their child to participate in research).

Informed Consent for Research Exempt from IRB Review

Although informed consent (or parental permission) should be obtained for research that is exempt from IRB review, documentation of such is not required. In fact, the IRB recommends against use of a consent document that asks for the participant's signature if the consent form is the only document that will identify the participant. Rather than using a consent form that includes a signature line, researchers should consider using a consent statement or script at the beginning of data collection. Appropriate wording for a consent statement for anonymous survey research is provided in the IRB document entitled "VSU Model Consent Statement for Anonymous Survey Research." This document may be modified for use with other types of exempt research.

Researchers conducting exempt studies that involve a topic of a sensitive nature may wish to document consent to meet requirements of a professional code of ethics. The researcher may use the IRB's model consent form or another format that is acceptable in the discipline. However, in all cases in which the IRB does not require documentation of informed consent (or parental permission), if reference to the IRB is made in a consent form, statement, or script, the following statement must be included:

"This study has been exempted from Institutional Review Board (IRB) review in accordance with Federal regulations. The IRB, a university committee established by federal law, is responsible for protecting the rights and welfare of research participants. If you have concerns or questions about your rights as a research participant, you may contact the IRB Administrator at 229-333-7837 or irb@valdosta.edu."

Documentation of Informed Consent/Parental Permission for Non-Exempt Research

When written documentation of consent is required by the IRB for non-exempt research and the participants are adults (*e.g.*, age 18 or older) who have the capacity to determine for themselves whether they wish to participate in the research, the **Model Consent Form** should be used. When participants are children, use the **Model Parental Permission Form** and the appropriate **assent** process for the minor participants (see below).

Requirements for Documentation of Informed Consent or Parental Permission

The consent document (or parental permission document) should be fully informative, reflect information conveyed verbally about the study, and be written in a language and at a readability level appropriate for the participant or parent. An 8th grade reading level is recommended for the general population. Most word processing packages can assess the readability of a document.

Unless the IRB has waived any or all of the elements of consent required by Federal regulations, the following elements must be explained verbally and must be included in the consent form. These elements are:

- ◆ A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the individual's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
- ◆ A description of any reasonably foreseeable risks or discomforts to the participant;
- ◆ A description of any benefits to the participant or to others which may reasonably be expected from the research;
- ◆ A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant;

- ◆ A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained;
- ◆ For research involving more than minimal risk, an explanation as to whether any compensation will be provided for participation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
- ◆ An explanation of whom to contact for answers to pertinent questions about the research and research participants' rights, and whom to contact in the event of a research-related injury to the participant; and
- ◆ A statement that participation is voluntary, refusal to participate will involve no loss of rights, benefits, or services to which the participant is otherwise entitled, and the participant may discontinue participation at any time without loss of rights, benefits, or services to which he/she is otherwise entitled.

Use of the Model Consent Form or Model Parental Permission Form ensures that all of the required elements of consent are addressed. To aid in efficient protocol review, the paragraph titles in the model consent documents should be retained. If the consent or permission form is more than one page, an area in the lower right hand corner of every page should be included for the participant's or parent's initials.

A copy of the consent document should be provided to the participant or parent; he/she does not need to sign the copy. The original consent/permission form should be stored in a secure location separate from data collected about participants and retained for at least three years (or longer if required by an external funding agency).

Child Assent for Non-Exempt Research

When the participants in non-exempt research are between the ages of 5-20, the IRB requires a participant assent process after parental permission has been granted.

Ages 5-12: For those participants who are ages 5-12, use the **Model Verbal Child Assent Script for Children Ages 5-12**. This assent script should be modified as necessary so that it can be easily understood by the particular participant population. Children in the 5-13 age range must give affirmative assent to participate. The lack of a negative reply is not sufficient to assume assent. Unless otherwise specified by the IRB, the child's signature indicating assent is optional.

Ages 13-20: The **Model Consent Form** normally used for adults may be modified and used as an assent form for children ages 13-20. A signature should be obtained from those minor participants who are 13 and older.

Under 5 Years of Age: Unless specifically required by the IRB during its protocol review and approval process, no formal assent process is required for children under 5 years of age. As appropriate, the researcher may ask the child if he/she wishes to play a game or complete some other activity, but, generally speaking, these young children exhibit their assent or refusal to participate through their behavior.

Children who do not assent should never be forced or coerced by their parents or the researcher to participate unless the study is providing some direct benefit to the child that cannot be attained through any other means. This type of situation rarely occurs in social/behavioral research.